NOV 1 3 2002

SECTION 2 K023008

SUMMARY AND CERTIFICATION

510(k) SUMMARY

Submitted by:

Scott Matovich
Quantum Medical Imaging, LLC.
2905 Veterans Memorial Highway
Ronkonkoma, NY 11779 USA

September 3, 2002

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Mark Camirand
Director of Q.A./Compliance
Phone: (631) 567-5800,
(631) 567-5074 (fax)

2. **Device Name and Classification:**

Trade Name:	QV-800 Universal System
Classification Name:	Stationary X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Device Code:	90KPR

3. **Intended Use:**

The Quantum Medical Imaging, LLC Universal System is a stationary radiographic imaging system used for acquiring radiographic images of various anatomical regions of the human body.

4. Substantially Equivalent Devices:

Quantum Medical Imaging, LLC. believes the QV-800 Universal System is substantially equivalent to the following commercially distributed devices; Cares Built Flex-Ray THESÉON (unknown 510(k) number) System and Pausch COSMOS-2 Universal X-Ray Unit (K870856).

5. Device Description:

The QV-800 Universal System is a wall- and floor-mounted column with an attached "swivel-arm". The QV-800 Universal System's "swivel-arm" design allows the x-ray tube and image receptor to remain in constant alignment as the arm is rotated and as the image receptor is angulated. The QV-800 Universal System is designed for use in hospitals, imaging centers, and clinics.

6. Summary of Technological Characteristics as Compared with Predicate Device(s):

The QV-800 Universal System has very similar technological characteristics as the predicate devices. The QV-800 Universal System fulfills its design requirements by providing the operator with the ability to perform safe and effective radiographic examinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Mr. Scott Matovich
President
Quantum Medical Imaging, LLC
2905 Veterans Memorial Highway
RONKONKOMA NY 11779

Re: K023008
Trade/Device Name: Universal System QV-800
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 KPR
Dated: September 3, 2002
Received: September 9, 2002

Dear Mr. Matovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023008

Device Name: QV-800 Universal System

Indications for Use:

The QV-800 Universal System is a stationary radiographic imaging system used for acquiring radiographic images of various anatomical regions of the human body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)

Division of [illegible]

[illegible]

510(k) Number K023008

(Optional Format 3-10-98)